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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,149	12/02/2003	David K. Swanson	015916-302	5299

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,149	Applicant(s) SWANSON, DAVID K.	
	Examiner Peter J. Vrettakos	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/18/05, 6/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Applicant is requested to check the beginning of the Specification with the Bib Data Sheet to ensure that the two lists the same priority information.

Pending claims are 1-47.

IDS filed 11/18/05 and 6/16/05 have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,7-8,10-16,18-19,21-28,30-32 and 34-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Francishelli et al. (6,706,038).

Francishelli discloses an apparatus (24, figure 1) for use with an electrophysiology device (20) that includes a coagulation element (22), the apparatus (24, figure 9) comprising: a main body (985); a suction region (col. 10:23-25; col. 11:44-60; array of 986 in figure 9) associated with the main body (985); a stimulation element (34 – see

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col. 16:23-26) on the main body (985 – runs through distal end of 24); and a connector (44) configured to secure at least a portion of the electrophysiology device (20) adjacent to the suction region (array of 986). See figure 1.

2. An apparatus as claimed in claim 1, wherein the suction region comprises a plurality (col. 11:45-46) of suction regions (986) and the stimulation element (34 alternate) comprises a plurality of stimulation elements. See figure 9.

3. An apparatus as claimed in claim 1, wherein the stimulation element (34 alternate) comprises a stimulation electrode (col. 16:23-24).

4. An apparatus as claimed in claim 1, wherein the stimulation element comprises a stimulation electrode pair (more than one element 34 shown in figure 9).

5. An apparatus as claimed in claim 1, further comprising: a sensing element (34, col. 5:41-42) on the main body in spaced relation to the stimulation element (34 alternate).

7. An apparatus as claimed in claim 5, wherein the sensing element (24 including 34) comprises a sensing electrode (“sensor 24 may serve as an electrode”, col. 5:63-64).

8. An apparatus as claimed in claim 5, wherein the sensing element comprises a

sensing electrode pair (col. 6:4-5 and/or col. 16:41-42).

10. An apparatus as claimed in claim 9, further comprising: a sensing element (34) on the main body (44) adjacent to the first suction port (986); wherein the stimulation (34 alternate) element is adjacent to the second suction port (986). See figure 9 and consider alternate disclosed uses of element 34 as seen in col. 16:23-26.

11. An apparatus as claimed in claim 1, wherein the connector (44) is configured to removably secure (due to suction ports 986) at least a portion of the electrophysiology device (20) adjacent to the suction region (array of 986).

12. A system (24 and suction source – col. 11:44) for use with an electrophysiology device (20) that includes a coagulation element (22), the system comprising: a suction source (col. 10:23-25; col. 11:44-60); and an apparatus (24), adapted to be operably connected to the suction source (col. 11:44-45), including a main body (985), a suction region (array of 986) associated with the main body, a stimulation element (34 – see col. 16:23-26) on the main body, and a connector (44) configured to secure (by suction) at least a portion of the electrophysiology device adjacent to the suction region.

13. A system as claimed in claim 12, wherein the suction region (array of 986) comprises a plurality (inherent to “array”) of suction regions and the stimulation element (34) comprises a plurality of stimulation elements (“electrodes” col. 16:24).

14. A system as claimed in claim 12, wherein the stimulation element (34) comprises a stimulation electrode (col. 16:23-26).

15. A system as claimed in claim 12, wherein the stimulation element comprises a stimulation electrode pair ("electrodes" col. 16:24).

16. A system as claimed in claim 12, further comprising: a sensing element (34) on the main body (985) in spaced relation to the stimulation (34 alternate) element. See figure 9.

18. A system as claimed in claim 16, wherein the sensing element (34) comprises a sensing electrode (depicted in figure 9).

19. A system as claimed in claim 16, wherein the sensing element (34) comprises a sensing electrode pair (depicted in figure 9).

21. A system as claimed in claim 20, further comprising: a sensing element (34) on the main body (985) adjacent to the first suction port (986); wherein the stimulation element (34 alternate) is adjacent to the second suction port (986).

22. A system as claimed in claim 12, wherein the connector (44) is configured to

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removably secure (through suction) at least a portion of the electrophysiology device (20) adjacent to the suction region (array of 986).

23. A system, comprising: an electrophysiology device including a support structure (distal end of 20 depicted in figure 1) and a coagulation element (22) carried on the support structure; and a stimulation apparatus (24,col. 16:23-26) including a main body (985), a suction region (array of 986) associated with the main body, a stimulation element (34 alternate) on the main body, and a connector (44) configured to secure at least a portion of the electrophysiology device adjacent to the suction region.

24. A system as claimed in claim 23, wherein the electrophysiological device support structure (distal end of 20 depicted in figure 1) defines a cross-sectional size and shape and the connector (44) defines a corresponding cross-sectional size and shape.

“Corresponding” in this context is broadly construed as being able to rest upon one another, which is the case with the flat connector 44 and the distal end of element 20 both seen in figure 1.

25. A system as claimed in claim 23, further comprising: a suction source (col. 11:43-44) adapted to be operably connected to the stimulation apparatus (24,col. 16:23-26).

26. A system as claimed in claim 23, further comprising: a stimulation energy source (80, col. 16:23-26) adapted to be operably connected to the stimulation apparatus

(24,col. 16:23-26).

27. A system as claimed in claim 23, further comprising: a coagulation energy source (30) adapted to be operably connected to the electrophysiology device (20). See figure 1.

28. A system as claimed in claim 23, wherein the electrophysiological device includes a plurality of spaced coagulation elements (22), the stimulation apparatus (34 alternate) includes a plurality of spaced stimulation elements, and the electrophysiological device and stimulation apparatus are respectively configured such that the coagulation elements will be adjacent to respective stimulation elements when the electrophysiology device is connected to the stimulation apparatus. Depicted in figure 1.

30. A system as claimed in claim 23, wherein the stimulation element comprises a stimulation electrode (col. 16:23-26).

31. A system as claimed in claim 23, wherein the stimulation element comprises a stimulation electrode pair ("electrodes" col. 16:24).

32. A system as claimed in claim 23, further comprising: a sensing element (34) on the main body (44) in spaced relation to the stimulation element (34 alternate). See figure 9.

34. A system as claimed in claim 32, wherein the sensing element (34) comprises a sensing electrode (depicted in figure 9).

36. A system as claimed in claim 32, wherein the sensing element (34) comprises a sensing electrode pair (depicted in figure 9).

37. A system as claimed in claim 23, further comprising: an electrophysiology recording apparatus adapted to be operably connected to the sensing element on the stimulation apparatus. See col. 16:23-26, "electrodes used to monitor the heart".

38. A system as claimed in claim 23, wherein the connector 44 is configured to removably secure (through suction) at least a portion of the electrophysiology device adjacent to the suction region.

39. A method, comprising the steps of: forming a lesion in tissue; securing a stimulation element to tissue adjacent to the lesion with a suction device; and transmitting stimulation energy to the tissue adjacent to the lesion. See patented claim 1 and all disclosure regarding the use of suction to help position pad (44).

40. A method as claimed in claim 39, wherein the step of forming a lesion comprises

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forming a lesion in tissue by supplying coagulation energy to the tissue. See patented claim 1. The Office equates for these purposes and in this context “ablating” with “coagulating”.

41. A method as claimed in claim 39, wherein the step of forming a lesion comprises forming a lesion in tissue by supplying coagulation energy to the tissue with an electrode.

42. A method as claimed in claim 39, wherein the step of forming a lesion comprises the steps of: positioning a distal portion of an electrophysiology device adjacent to tissue; applying a suction force to the tissue with a suction device secured to the electrophysiology device; and forming a lesion with the electrophysiology device in the tissue while the suction force is being applied. This is depicted in figure 1.

43. A method as claimed in claim 42, wherein the step of securing a stimulation element to tissue comprises: positioning a stimulation element (34 alternate, again see col. 16:23-26) carried on the suction device adjacent to the lesion; applying a suction force to the tissue with a suction device; transmitting stimulation energy (34 alternate, again see col. 16:23-26) to the tissue adjacent to the lesion while the suction force is being applied. This is depicted in figure 1.

44. A method as claimed in claim 39, further comprising the step of: monitoring

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(temperature sensing with 34) tissue after transmitting stimulation energy to the tissue.

See figure 11.

45. A method as claimed in claim 44, wherein the step of monitoring tissue comprises sensing (34) a local excitation caused by the stimulation energy. "Monitoring," disclosed in col. 16:23-26.

46. A method as claimed in claim 44, wherein the step of transmitting stimulation energy comprises transmitting stimulation energy to tissue on one side of the lesion; and wherein the step of monitoring tissue comprises monitoring tissue on the other side of the lesion. "Assess transmural" disclosed in col. 6:33.

47. A method as claimed in claim 46, wherein the step of monitoring tissue comprises monitoring tissue on the other side of the lesion to determine a propagation delay. See col. 6:30-35 where the patent discloses an intended purpose for the patented device being to "control an arrhythmia". Arrhythmias are any change in the rate of electrical propagation and therefore controlling a change in electrical propagation anticipates determining a propagation delay.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 9, 17, 20, 29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francishelli.

Claims are merely about the location on the device of stimulating elements, sensing elements, and suction elements. The patent discloses much flexibility toward these elements' placements as well as uses (stimulate or sense). See col. 12:6-22 and col. 16:23-26. Through routine experimentation, the Applicant's claims would have been deduced. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Francishelli by using different placements to increase the number of applications for which the device could be used. The patent through its disclosure of flexibility regarding suction port, stimulating element, and sensing element placement, use, and shapes implies this motivation.

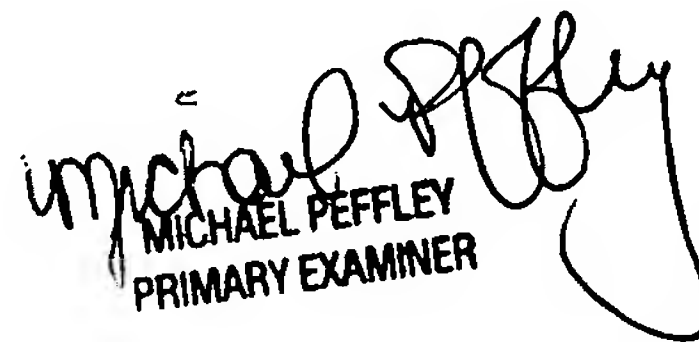
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
January 6, 2006



MICHAEL PEFFLEY
PRIMARY EXAMINER